# FOOD AND DRUG ADMINISTRATION CENTER FOR BIOLOGICS EVALUATION AND RESEARCH

### VACCINES AND RELATED BIOLOGICAL PRODUCTS ADVISORY COMMITTEE

## September 14 – 15, 1999 Holiday Inn, Bethesda, Maryland

## Tuesday, September 14, 1999

# DRAFT

1 PM		Session 1: Update on Thimerosal – Ope	e <u>n session</u> Dr. William Egan, FDA
1:15		Session 2: Update on Cell Substrate W	orkshop – Open Session Dr. Andrew Lewis, FDA
1:30		Session 3: Update on RotaShield – Ope	en Session Dr. Kathryn Carbone, FDA
1:40 Session 4: Briefing on Selected Individual Res			ual Research Programs – Open Session
	1:40	Introduction	Dr.Thomas Hoffman
	1:50	Laboratory of Parasitic Biology and Biochemistry	Dr. Richard Kenney
	2:00	Laboratory of Biophysics	Dr. Richard Pastor
2:10		Open Public Hearing	
2:50	,	Break	
3:10		Session 5: - CLOSED session	
4:00		Session 6: - CLOSED Session	
5:00		Adjourn for the day	

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**DRAFT** 

# Wednesday; September 15, 1999

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8 AM	Session 7: Use of Immunologic Surrogates for Demonstration of Protective Efficacy of Meningococcal Conjugate Vaccines – Open Session				
	8:00	Call to order and announcements	Dr. Harry Greenberg		
	8:15	Introduction to the Topic	Dr. Carl Frasch, FDA		
	8:25	Epidemiology of Group C Meningococcal Disease in the US and Other Countries	Dr. Bradley Perkins, CDC		
	9:05	Correlation of Bactericidal Antibody with Protection against Meningococcal Disease	Dr. Emil Gotschlich		
	9:45	Break			
	10:05	Standardized and Validated Immuno- assays for Group C Measurement of Group C Polysaccharide Antibodies for Bactericidal and ELIZA	Dr. George Carlone, CDC		
	10:45	Presentation by Connaught			
	11:05	Presentation by Chiron			
	11:25	Presentation by North American Vaccine			
	11:45	FDA presentation	Dr. Carl Frasch, FDA		
	12:10	Open Public Hearing			
	12:30	Lunch			
	1:30	Reintroduction of the Questions	Dr. Carl Frasch, FDA		
	1:40	General Discussion			
	2:10	Committee Discussion of the Questions			
3:15		Adjournment			